PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

Document Name: Performance Qualification Test Datasheet # 3.5 for Lyophilizer	
Equipment/System ID:	**Document Number:**
Effective Date:-	**Version Number:** 00

Test ID #3.5: Temperature Mapping During Empty Lyophilization Cycle	**Test Run: ____**
Target:	The objective of this test is to ensure that the temperature distribution during the Empty Lyophilization cycle in each shelf as per the set parameter and is uniform at all locations and gives assurance of uniform temperature distribution in product during the Lyophilization of the product.
Necessary materials:	• Calibrated Data logger • Calibrated T-type temperature sensors • Brass dies or Aluminium dies
Preconditions:	Equipment should be normal operational mode

Test ID	**Test Description**
1.	Before the study ensures that the lyophilizer is at ambient temperature.
2.	Ensure that the temperature probes and data logger are calibrated.
3.	Prepare at least 43 Nos. calibrated temperature mapping probe with location and channel tag.
4.	Put the required no of probes inside the lyophilizer through the validation port of lyophilizer considering probes considering 5 probes for top and bottom shelf and 3 probes per shelf.
5.	Perform full loop calibration (sensor + data logger) before starting the qualification runs. Attach calibration reports. If external agency is carrying out the test the calibration certificate will be referred.
6.	Pass 43 nos. Temperature mapping sensors into chamber through the validation port of the Lyophilizer. Distribute the sensors as per the Drawing mentioned in Appendix No: 3.5.1. Seal the port with silicone sealant. Distribute the probes with dies at each shelf as per mentioned **Drawing No. 1**in **Appendix 3.5.1**.Label the thermocouples by number using a strip of autoclavable tape, this ensures the location of the thermocouple for which the data is recorded. Record the position of the probes in a representative schematic form.
7.	Connect the probes to a suitable data logger, which can scan and print the actual temperature observed at different locations with respect to time.
8.	Set the data logging time for 05 sec. in data logger. Start the data logger and start the Lyophilization cycle as per the SOP. Record the temperature of all 43 sensors in the data logger.
9.	Record the probe location in the datasheet.
10.	Close the main door.
11.	Set the recipe in the SCADA of lyophilizer as per Appendix: 3.5.1.
12.	Record the recipe parameter in the datasheet.
13.	Set the data logging time in the lyophilizer as 01 minute.
14.	After the cycle is over take the printout of report generated and data logging report from the data logger.
15.	If the empty chamber temperature mapping study is acceptable perform two more consecutive replicate runs to demonstrate cycle and Lyophilizer reproducibility.
16.	Compile the data generated during the qualification test for complete evaluation of the system.

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

Document Name: Performance Qualification Test Datasheet # 3.5 for Lyophilizer	
Equipment/System ID:	**Document Number:**
Effective Date:-	**Version Number:** 00

Test ID #3.5: Temperature Mapping During Empty Lyophilization Cycle	**Test Run: ____**
17.	After the cycles is over ensure that the post calibration of probes is done.
18.	Record the observations & data as per Appendix 3.5.1.
19.	Attach the print out of the test cycle taken from the Lyophilizer with this data sheet.

	Acceptance criteria	**Acceptance criteria fulfilled? (Y/N)**
1.	The Shelf inlet temperature and shelf outlet temperature probes should not vary more than ±2° C.	
2.	The shelf temperature should control within ± 2°C to each set point once system is stabilized.	
3.	The shelf inlet probe temperature average should not vary by more than 1.5 °C from the set temperature as per the recipe.	
4.	The average of all external probe temperature on each shelf should not vary more than ±2° C from the average of all inbuilt sensors temperature during hold time.	
5.	The cycle should run in a similar sequence as per the recipe.	
6.	The report generated should be in a similar sequence as per the recipe	
7.		
Measures after test execution:	Allow all the sensors to cool to ambient temperature before starting the next cycle.	

Comment Ref. No	**Comment**	**Deviation Ref No**

Checked by (Signature/ Date)		**Verified by (Signature/Date)**	